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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,885	07/24/2000	Albert Edge	DNI-029	6245

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LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/624,885

Applicant(s)

EDGE, ALBERT

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 20-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election without traverse of Group I (Claims 1-19) in Paper No. 7 filed 1-4-02, is acknowledged.
2. Claims 20-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7, filed 1-4-02.

### *Drawings*

3. New formal drawings are required in this application because of the reasons set forth on the attached PTO Form 948. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### 1. **Correction of Informalities – 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

#### 2. **Corrections other than Informalities Noted by Draftsman on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsman, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

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### Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

### *Claim Rejections – 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition wherein the skeletal myoblast cells are induced to become more like cardiac cells by engineering the skeletal myoblast cells to express a GATA transcription factor, does not reasonably provide enablement for a composition wherein the skeletal myoblast cells are induced to become more like cardiac cells by any other method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 17 is drawn to a composition wherein the skeletal myoblast cells are induced to become more like cardiac cells. The instant specification discloses on page 6 that the phrase "more like cardiac cells" includes skeletal muscle cells which are made to more closely resemble cardiac muscle cells in phenotype. However, the only composition disclosed in the instant specification wherein the skeletal myoblast cells are induced to become more like cardiac cells, are cells transfected with a GATA 4 or GATA 6 transcription factor. Grepin et al (1997)(IDS) teaches that little is known about the molecular signals that are involved in the specification and survival of cardioblasts. Using P19 embryonic stem cells Grepin et al teach that GATA4 accelerates cardiogenesis in P19 cells, that without GATA4 differentiation is blocked at the cardiac blast stage and that GATA-6 could fully compensate for GATA-4 (see entire article, including the Abstract, and the Discussion section, especially the first paragraph of the discussion section and the first full paragraph of column 2 of page 2393). WO 9512979 (IDS) teaches that it is possible to convert non-myocytes such as fibroblasts to a muscle phenotype by injection of a vector expressing a muscle regulatory factor gene, but teaches no other method of cell conversion. Therefore, without further guidance and direction from the instant specification, it would be undue experimentation for one of skill to make a composition wherein the skeletal myoblast cells are induced to become more like cardiac cells, by any method other than by engineering the skeletal myoblast

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cells to express a GATA-4 or GATA-6 transcription factor which is a muscle regulatory factor gene.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-5 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Mickle et al (US Patent 6,099,832 and WO 98/54301)(IDS).

Mickle et al teach a composition of cells comprising fetal smooth muscle cells and fibroblasts for forming a stable myocardial graft (see column 2, first three paragraphs of US Patent 6,099,832, and last three paragraphs of WO 98/54301). Said cells are autologous, having been isolated from rat and transplanted into rat. Although the exact percentage of each type of cells in the transplantable composition was not taught, the reference anticipates the recitation of about 20% to about 70% skeletal myoblast cells, due to the recitation of the term "about". Mickle et al also teach that the cells were cultured prior to transplantation (see column 16, lines 25-31). Therefore, the referenced teachings anticipate the claimed invention.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-19 are indefinite in their recitation of a "transplantable composition" because the characteristics that make a composition transplantable are not clear.

B) Claim 16 is indefinite in its recitation of "cells engineered to express an angiogenic gene product" because it is not clear if the said engineered cells refer to the skeletal myoblast and fibroblast cells recited in base claim 1, or if the engineered cells refer to additional cells.

11. Claims 6-19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
Art Unit 1644,  
Group 1640,  
March 25, 2002

*Amy DeCloux 3-28-02*